

PTO/SB/08 (Modified)

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/685,323 |
| Filing Date | 10/14/2003 |
| First Named Inventor | Franck J. BARRAT |
| Art Unit | 1644 |
| Examiner Name | M.A. Belyavskiy |
| Attorney Docket Number | DX01177B |

Sheet 1 of 3

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | DOCUMENT NUMBER | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant, Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|--|
| | | Number-Kind Code ² (if known) | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |

FOREIGN PATENT DOCUMENTS


| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant, Passages or Relevant Figures Appear | T ⁶ |
|-----------------------|--------------------------|---|--------------------------------|--|--|----------------|
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| MA | AA | WO 91/04030 | 04-04-1991 | R.A. DAYNES, et al. | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| | | | |
|-----------------------|--|--------------------|---------|
| Examiner Signature | | Date Considered | 2/28/06 |
|-----------------------|--|--------------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.

| | | | | | |
|--|---|----|---|--------------------------|------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/685,323 |
| | | | | Filing Date | 10/14/2003 |
| | | | | First Named Inventor | Franck J. BARRAT |
| | | | | Art Unit | 1644 |
| | | | | Examiner Name | M.A. Belyavskyi |
| Sheet | 2 | of | 3 | Attorney Docket Number | DX01177B |

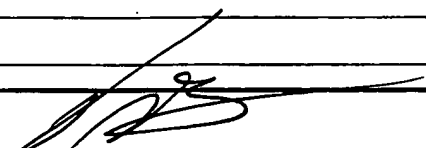
| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| MB | AB | M. HELOISA BLOTTA, et al., <u>J Immunol</u> , 158(12):5589-5595, June 15, 1997. "Corticosteroids inhibit IL-12 production in human monocytes and enhance their capacity to induce IL-4 synthesis in CD4+ lymphocytes" | |
| | AC | FRANK BRIDOUX, et al., <u>J Exp Med</u> , 185(10):1769-1775, May 19, 1997. "Transforming growth factor beta (TGF-beta)-dependent inhibition of T helper cell 2 (Th2)-induced autoimmunity by self-major histocompatibility complex (MHC) class II-specific, regulatory CD4(+) T cell lines" | |
| | AD | JAN BUER, et al., <u>J Exp Med</u> , 187(2):177-183, January 19, 1998. "Interleukin 10 secretion and impaired effector function of major histocompatibility complex class II-restricted T cells anergized in vivo" | |
| | AE | NITYA G. CHAKRABORTY, et al., <u>J Immunol</u> , 162(9):5576-5583, May 1, 1999. "Emergence of regulatory CD4+ T cell response to repetitive stimulation with antigen-presenting cells in vitro: implications in designing antigen-presenting cell-based tumor vaccines" | |
| | AF | RONGBING CHEN, et al., <u>J Immunol</u> , 164(2):825-832, January 15, 2000. Glucocorticoids inhibit calcium- and calcineurin-dependent activation of the human IL-4 promoter" | |
| | AG | DANIELE D'AMBROSIO, et al., <u>J Clin Invest</u> , 101(1):252-262, January 1, 1998. "Inhibition of IL-12 production by 1,25-dihydroxyvitamin D3. Involvement of NF-kappaB downregulation in transcriptional repression of the p40 gene" | |
| | AH | KAROLIEN DE BOSSCHER, et al., <u>Proc Natl Acad Sci U S A</u> , 94(25):13504-13509, December 9, 1997. "Glucocorticoid-mediated repression of nuclear factor-kappaB-dependent transcription involves direct interference with transactivation" | |
| | AI | HERVE GROUX, et al., <u>Nature</u> , 389(6652):737-742, October 16, 1997. "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis" | |
| | AJ | GIANDOMENICA IEZZI, et al., <u>Eur J Immunol</u> , 29(12):4092-4101, December 1999. "The interplay between the duration of TCR and cytokine signaling determines T cell polarization" | |
| | AK | MICHAEL KARIN, <u>Cell</u> , 93(4):487-490, May 15, 1998. "New twists in gene regulation by glucocorticoid receptor: is DNA binding dispensable?" | |
| MB | AL | UI YEN KHOO, et al., <u>J Immunol</u> , 158(8):3626-3634, April 15, 1997. "CD4+ T cell down-regulation in human intestinal mucosa: evidence for intestinal tolerance to luminal bacterial antigens." | |

| | | | |
|--------------------|---|-----------------|---------|
| Examiner Signature |  | Date Considered | 2/28/06 |
|--------------------|---|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.

| | | | | | |
|---|---|----|---|--------------------------|------------------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/685,323 |
| | | | | Filing Date | 10/14/2003 |
| | | | | First Named Inventor | Franck J. BARRAT |
| | | | | Art Unit | 1644 |
| | | | | Examiner Name | M.A. Belyavskyi |
| Sheet | 3 | of | 3 | Attorney Docket Number | DX01177B |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| M/B | AM | FRANK MATTNER, et al., <u>Eur J Immunol</u> , 30(2):498-508, February 2000. "Inhibition of Th1 development and treatment of chronic-relapsing experimental allergic encephalomyelitis by a non-hypercalcemic analogue of 1,25-dihydroxyvitamin D(3)" | | |
| | AN | CARLA MILLER, et al., <u>J Exp Med</u> , 190(1):53-64, July 5, 1999. "Anergy and cytokine-mediated suppression as distinct superantigen-induced tolerance mechanisms in vivo" | | |
| | AO | ANNE O'GARRA, <u>Immunity</u> , 8(3):275-283, March 1998. "Cytokines induce the development of functionally heterogeneous T helper cell subsets" | | |
| | AP | LORENZO PIEMONTI, et al., <u>J Immunol</u> , 164(9):4443-4451, May 1, 2000. "Vitamin D3 affects differentiation, maturation, and function of human monocyte-derived dendritic cells" | | |
| | AQ | FRANCISCO RAMIREZ, et al., <u>J Immunol</u> , 156(7):2406-2412, April 1, 1996. "Glucocorticoids promote a TH2 cytokine response by CD4+ T cells in vitro" | | |
| | AR | DAVID F. RICHARDS, et al., <u>Eur J Immunol</u> , 30(8):2344-2354, August 2000. "Glucocorticoids drive human CD8(+) T cell differentiation towards a phenotype with high IL-10 and reduced IL-4, IL-5 and IL-13 production" | | |
| | AS | CHAO-ZHONG SONG, et al., <u>Proc Natl Acad Sci U S A</u> , 96(21):11776-11781, October 12, 1999. "Glucocorticoid receptor inhibits transforming growth factor-beta signaling by directly targeting the transcriptional activation function of Smad3" | | |
| | AT | PEDRO L. VIEIRA, et al., <u>J Immunol</u> , 161(10):5245-5251, November 15, 1998. "Glucocorticoids inhibit bioactive IL-12p70 production by in vitro-generated human dendritic cells without affecting their T cell stimulatory potential" | | |
| | AU | JEROEN VISSER, et al., <u>Blood</u> , 91(11):4255-4264, June 1, 1998. "Differential regulation of interleukin-10 (IL-10) and IL-12 by glucocorticoids in vitro" | | |
| | AV | THOMAS WILCKENS and ROEL DE RIJK, <u>Immunol Today</u> , 18(9):418-424, September 1997. "Glucocorticoids and immune function: unknown dimensions and new frontiers" | | |
| M/B | AW | JUNN YANAGISAWA, et al., <u>Science</u> , 283(5406):1317-1321, February 26, 1999. "Convergence of transforming growth factor-beta and vitamin D signaling pathways on SMAD transcriptional coactivators" | | |
| | | | | |
| | | | | |

| | | | |
|--------------------|---|-----------------|---------|
| Examiner Signature |  | Date Considered | 2/28/06 |
|--------------------|---|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.